Citation:

Chen CW, Lin YL, Lin TK, Lin CT, Chen BC, Lin CL. Total cardiovascular risk profile of Taiwanese vegetarians. *Eur J Clin Nutr.* 2008 Jan;62(1):138-44. Epub 2007 Mar 14.

PubMed ID: 17356561

Study Design:

Cohort study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare serum homocysteine and hs-CRP levels, as well as conventional risk factors between Taiwanese vegetarians and omnivores to define better the cardiovascular protective effects of Taiwanese vegetarian diets.

Inclusion Criteria:

- Must have undergone a general health exam at the Buddhist Dalin Tzu-Chi General Hospital from December 12, 2004 to March 25, 2005.
- Article states "subject filled out questionnaires regarding their past medical history, dietary preferences and their willingness to participate in the study were enrolled in they met the inclusion criteria" but no other inclusion criteria were discussed.
- Must have been on an ovo-lactovegetarian diet for at least 1 year to be enrolled into the vegetarian group

Exclusion Criteria:

Patients were excluded if they had any of the following within 3 weeks before the start of the study:

- Diabetes
- Hypertension
- Cerebrovascular disease
- Dyslipidemia
- Chronic gingivitis
- Rheumatoid arthritis or other connective tissue disease
- Diagnosis of coronary artery disease
- Fever
- Other infectious disease

Description of Study Protocol:

Recruitment

- Must have undergone a general health exam at the Buddhist Dalin Tzu-Chi General Hospital from December 12, 2004 to March 25, 2005.
- Enrolled on a "first come, first served" basis until the number in both groups (99 vegetarians and 99 omnivores) were filled.

Design: Cohort Study

Blinding used (if applicable): not applicable

Intervention (if applicable): not applicable

Statistical Analysis

- Differences in the two groups were compared with parametric independent samples t-test and nonparametric Mann-Whitney U-test
- x^2 test was used for categorical variables
- Pearson correlation coefficient used to analyze relationship between two groups

Data Collection Summary:

Timing of Measurements

- After an overnight fast (more than 12 hours), venous blood samples were obtained from 99 vegetarians (group A) and 99 omnivores (group B).
- Blood samples were immediately tested after being taken.

Dependent Variables

- High sensitivity C-reactive protein (hs-CRP) - assayed using an enzyme-linked immunosorbent assay (ELISA), based on purified protein and polyclonal anti-C-reactive protein antibodies
- Blood samples analyzed for glucose, cholesterol, triglyceride, HDL cholesterol, LDL cholesterol, white blood cell count, homocysteine, uric acid
- Systolic and diastolic blood pressures

Independent Variables

- Omnivore diet
- Vegetarian diet

Control Variables

- Age
- Smoking status

Description of Actual Data Sample:

Initial N: 198 total

- 99 vegetarians (34 male and 65 female)
- 99 omnivores (53 male and 46 female)

Attrition (final N): none described, all 198 accounted for in results

Age: adults over 20 years old

- Vegetarians: 51.24 ± 8.88 years
- Omnivores: 49.38 ± 9.60 years

Ethnicity: Taiwanese

Other relevant demographics:

	Vegetarians	Omnivores	P-Value
Smoke			
Yes	11(11.1%)	22(22.2%)	0.036*
No	88(88.9%)	77(77.8%)	
Gender			
Male	34(34.3%)	53(53.5%)	0.007*
Female	65(65.7%)	46(46.5%)	

*Statistical significance set at P-value <0.05

Anthropometrics

Body weight (kg)

- Vegetarians: 58.66 ± 11.13
- Omnivores: 62.88 ± 12.24
- P-value: 0.012

Body Height (cm)

- Vegetarians: 159.14 ± 7.88
- Omnivores: 162.53 ± 8.14
- P-value: 0.03

Body Mass Index (kg/m^2)

- Vegetarians: 22.9 ± 2.81
- Omnivores: 23.79 ± 3.56

Location: Chia-Yi, Taiwan, Republic of China

Summary of Results:

Key Findings

- There was no significant difference in age, BMI, blood glucose, white blood cell count, triglyceride and HDL-cholesterol between the two groups

- The vegetarian group had significantly more females (65.7% vs 46.5%), lower body weight (58.66 ± 11.13 vs 62.88 ± 12.24 kg), shorter height (159.14 ± 7.88 vs 162.53 ± 8.14 cm), lower total cholesterol (184.74 ± 33.23 vs 202.01 ± 41.05 mg/dl), and lower LDL-cholesterol (119.63 ± 31.59 vs 135.89 ± 39.50 mg/dl).
- Hs-CRP was significantly lower (0.14 ± 0.23 vs 0.23 ± 0.44 mg/dl, P = 0.025), whereas homocysteine was significantly higher (10.97 ± 6.69 vs 8.44 ± 2.50 μmol/L, P = 0.001) in vegetarians than omnivores.

Variables	Vegetarians	Omnivores	P-Value
	Mean±s.d	Mean±s.d	
Systolic Blood Pressure (mm Hg)	120.49±15.63	125.55±15.04	0.022
Diastolic Blood Pressure (mm Hg)	75.01±11.90	78.76±11.71	0.027
Uric Acid (mg/dL)	5.05±1.44	5.61±1.38	0.006
Cholesterol (mg/dl)	184.74±33.23	202.01±41.05	0.001
Triglyceride (mg/dl)	95.93±65.53	102.71±78.94	0.059
HDL-C (mg/dl)	56.16±15.20	55.62±14.50	0.796
LDL-C (mg/dl)	119.63±31.59	135.89±39.50	0.002
Glucose (mg/dl)	89.90±10.65	90.22±16.01	0.826
WBC (103/μl)	6.40±1.38	6.54±1.56	0.495
hs-CRP (mg/dl)	0.14±0.23	0.23±0.44	0.025
Homocysteine (μmol/l)	10.97±6.69	8.44±2.50	0.001

Other Findings

Gender differences in homocysteine level were found statistically different

	Male, μmol/l(N)	Female, μmol/l(N)	P-Value
Vegetarians (n=99)	15.00±9.74(34)	8.86±2.55(65)	<0.001
Omnivores (n=99)	9.82±2.40(53)	6.85±1.46(46)	0.011

After comparing vegetarian and omnivore males and vegetarian and omnivore females separately, statistically significant differences were found in total cholesterol,LDL-C and homocysteine in males.

Variables	Vegetarians	Omnivores	P-Value
	Mean±s.d	Mean±s.d	
Cholesterol (mg/dl)	183.85±33.63	201.36±37.28	0.029
LDL-C (mg/dl)	120.44±28.94	138.98±35.74	0.013
Homocysteine (μmol/l)	15.00±9.74	9.82±2.40	0.001

Female vegetarians had significantly lower uric acid and total cholesterol levels, and significantly higher homocysteine levels.

Female Variables	Vegetarians	Omnivores	P-Value
	Mean±s.d	Mean±s.d	
Uric Acid (mg/dl)	4.34±0.94	4.92±1.06	0.003
Cholesterol (mg/dl)	185.20±33.28	202.76±45.42	0.020
Homocysteine (μmol/l)	8.86±2.55	6.85±1.46	<0.001

Author Conclusion:

- Taiwanese vegetarians had a lower hs-CRP level, lower blood pressure, lower total cholesterol and lower HDL-C than omnivores. However, homocysteine levels were higher in vegetarians. Owing to different predictive value of each risk factor, we believe the Taiwanese vegetarians had a better cardiovascular risk profile than omnivores.
- Whether Taiwanese vegetarian diets should be supplemented with vitamin B12 to lower serum homocysteine levels remains to be addressed.
- Further studies, especially long-term follow up data to develop CHD risk prediction algorithms suited for Taiwanese population, are needed.

Reviewer Comments:

- *It states that questionnaires were asked regarding dietary preferences but no data is described. No extra detail was given on exposure to vegetarian diet.*
- *It would have been helpful to see some diet analysis, even in the form of a Diet History Questionnaire (similar to that of the National Cancer Institute questionnaire).*
- *There is also no data regarding family history of cardiovascular disease and no data of any other risk factors such as exercise or caffeine use*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes

3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes

6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	???
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	???
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	N/A
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes

8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes